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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Giorgio Rosati

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EXAMINER

GUPTA, VANI

ART UNIT

PAPER NUMBER

3777

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/594,802	ROSATI, GIORGIO	
	<b>Examiner</b>	<b>Art Unit</b>	
	VANI GUPTA	3777	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2012.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 1,4,6 and 8-20 is/are pending in the application.
- 5a) Of the above claim(s) 12-17 is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1,4,6,8-11 and 18-20 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**1. Claims 1, 4, 6, 11, and 20 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Wilson et al. (US 6, 656,189 B1).**

**Regarding Claim 1**, Wilson et al. (hereinafter Wilson) suggests an automatic pointing apparatus for correct positioning of distal locking screws of an intramedullary nail comprising a hole, the automatic pointing apparatus comprising:

means for receiving one or more images of a portion of the intramedullary nail (**61**) to be fixed with the screws, the one or more images showing the hole (**8**); means for processing the one or more images to obtain coordinates of the center of the hole and inclination of an axis of the hole; and means for positioning a surgical instrument (*trocar - (30); drill - (50)*) in correspondence with the axis of said hole, and align the instrument with the axis (col. 2, line 1 – col. 3, line 5; col. 6, line 31 – col. 7, line 31);

a head (*figs. 1 and 2*, assembled, as shown in *fig. 6*. *Fig. 6* includes assembly of *fig. 3* – surgical instrument, as well) which includes a reference system (20) comprising one or more radiopaque bodies of known shape, dimensions and position ((7), (13), (23)); col. 4, ll. 41 – 67;

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protection sleeve is also made of radiopaque material, except (23) that is made of different radiopaque material...shape and dimensions and position are thus known), incorporated in the head to be viewed by an x-ray viewing apparatus (71), and guidance means ((1); see *figs. 1 and 6* again), included in said head, for guiding said surgical instrument (trocar, drill; as described in col. 5, l. 28 – col. 7, line 9);

means for moving said head close to an end of the nail comprising the hole; means for taking, by said X-ray, fluoroscopic or similar apparatus, simultaneous images of the end of the nail comprising the hole for the distal locking screws and of the reference system (see rejection of claim 1; col. 4, line 67 – col. 6, line 10; *figs. 6 - 8*); and

means for reading the images and calculating position and inclination of the axis of the hole based on shape and dimensions of the hole shown in the images (col. 5, ll. 3 – 8 and col. 5, line 27 – col. 6, line 57). The “dark circle” is used to align the aiming guide, associated it with the head, with the nail hole. Since it is known that the longitudinal axis of the reference system aligns parallel with the x-ray beam for the dark circle to appear (col. 5, ll. 3 – 8), and the dark circle represents the alignment of the instrument and reference system, and is used to assist in ensuring proper alignment of these components with the hole, and the dark circles are “superimposed on the over the circular image of the nail hole (col. 5, ll. 28 – 41), the position and inclination of the axis of the hole would also be realized based on the same image depicting the dark circles. Col. 5, line 42 – col. 6, line 57 provides additional supportive details.

There is also means for reading the images and calculating relative position and inclination of the reference system, and consequently of the head, based on shape and

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dimensions of the reference system (see just above; and col. 4, ll. 59 – 62; col. 5, line 14 – col. 6, line 10).

There is also means for calculating by a suitable algorithm (interpreted to include manual step or procedure) position and inclination of the axis of the hole relative to the reference system (see previous two sets of citations; col. 5, ll. 3 – 8); and

means for moving the head so as to provide the means for guiding the surgical instrument with an inclination that is the same as the inclination of the axis of the hole (see above citations and col. 4, l. 56 – col. 6, line 44).

**Regarding Claim 4**, The pointing apparatus as claimed in claim 1, wherein the X-ray, fluoroscopic or similar apparatus have an output for an analogue or digital signal which allows the images taken by the same apparatus to be displayed on a computer or other similar apparatus (on x-ray monitor/converter (**71**)). It should be noted that these aspects would be known and/or inherent to the art of using monitors to display image data. External viewing apparatus (X-ray monitor, (**71**)) would inherently comprise an interface or display screen; and would inherently comprise connectivity to the imaging device to receive the outputted analog/digital image data from imaging apparatus (x-ray machine) for displaying the image data on the display screen.

**Regarding Claim 6**, Wilson suggests the pointing apparatus as claimed in claim 1, wherein the head with the reference system is connectable to a respective support via “screwing” action (col. 6, ll. 11 – 13). As would be understood by one of ordinary skill in the art (e.g. mechanical engineering), if one was to unscrew Wilson’s components, the arrangement of the head and reference system would fall apart, or release from each other, relatively quickly.

**Regarding Claim 11**, Wilson suggests the pointing apparatus as claimed in claim 2 further comprising a sterile hood, capable of being fitted to the head, the sterile hood capable of being designed to cover the supports of the head and other parts of the pointing apparatus in the zone of an operating field (col. 6, ll. 1 – 2).

**Regarding Claim 20**, Wilson suggests the pointing apparatus as claimed in claim 1, further comprising a terminal designed to support in said head, the surgical instrument guidance means (*fig. 1, (10) and (21)*).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**2. Claims 8 – 10 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson as applied to claim 1 above.**

**Regarding Claim 8**, with respect to the pointing apparatus as claimed in claim 1 wherein the radiopaque elements are spheres, this would be an obviousness matter of design choice. See *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant). Furthermore, since applicant has not disclosed that providing spherically shaped radiopaque markers solves any stated problem or is

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for any particular purpose and it appears that the invention would perform equally well with the size and/or shape of radiopaque markers provided by Wilson.

**Regarding Claim 9**, with respect to the pointing apparatus as claimed in claim 8 wherein the spheres are located at vertices of polygons, Applicant should note that this entails mere arrangement of parts, which does not receive any patentable weight because it would not produce any unexpected results. See *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950).

Nonetheless, it would be prima facie obvious to modify Wilson to provide such an arrangement so that one may optimize on localizing/placement of the surgical instrument in the hole(s) of the nail. With respect to providing the markers at vertices of polygons *of known dimensions*, see In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

**Regarding Claim 10**, Wilson suggests the pointing apparatus as claimed in claim 3 wherein the head and the reference system are mounted on a support (*I*) comprising a plurality of numerically controlled actuators designed to control translation of the head and the reference system according to at least two linear directions orthogonal to one another and to control rotation of the head and the reference system around at least two non-parallel axes. Wilson provides teachings for manual translation, alignment, rotation, etc. of the head (col. 5, line 34 - 41; col. 6, ll. 11 - 30). It should be noted that it would have been obvious to one of ordinary skill in the art to modify Wilson to provide “automated” or digitized means, or other kinds of external

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control means, for performing translation, alignment, rotation, etc., and doing so would not receive any patentable weight, since it has been held broadly that providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art, and involves only routine skill in the art. See *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).

**Regarding Claim 18**, it would be obvious to one skilled in the art that if Wilson is determining proper alignment of the axis of reference system and, therefore, the drill bit with the axis of the nail hole to ensure proper drilling of a hole “through the nail hole and surrounding bone material” (col. 6, ll. 50 – 57; and *fig. 8*), and Wilson is then inserting the distal locking screws into these drilled holes and “through the bone” (col. 7, ll. 20 – 31), then Wilson is also providing means for calculating the optimum length the drill hole of a distal locking screw from the coordinates and inclination, relative to the reference system, of the axis of the hole for the distal locking screws. It should be noted that whether Wilson is automatically or manually performing this step, it has been held broadly that providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art, and involves only routine skill in the art. See *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).

**3. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson as applied to claim 1 above, and further in view of Bennett (US 6,491,714 B1).**

**Regarding claim 19**, Wilson teaches each and every limitation of the claim, as discussed above in reference to claim 1.



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However, Wilson differs from Claim 19 in that Wilson does not teach the pointing apparatus as claimed, wherein the surgical instrument guidance means comprise a cannula..

Nonetheless, Bennett teaches using a cannula as a guide to position the drill guide and drill over the bone to drill a hole through the bone (col. 3, line 54 – col. 4, line 15).

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Wilson and Bennett before one at the time the invention was made, to modify the apparatus with reference system with bone drill of Wilson with the drilling of bone via cannula guiding teachings of Bennett to provide additional support, and therefore more ease of use, to the user of Wilson's apparatus.

#### ***Response to Arguments***

4. Applicant's arguments filed January 6, 2012 have been fully considered but they are not persuasive.

Applicants submit that Wilson does not teach or suggest *"means for reading the images and calculating position and inclination of the axis of the hole based on shape and dimensions of the hole shown in the images"*, and *"means for reading the images and calculating relative position and inclination of the reference system, and consequently of the head, based on shape and dimensions of the reference system"* and *"means for calculating by a suitable algorithm position and inclination of the axis of the hole relative to the reference system"*, and *"means for moving the head so as to provide the means for guiding the surgical instrument with an inclination that is the same as the inclination of the axis of the hole"* as recited in claim 1.

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(Emphasis added). Applicant summarizes also parts of Wilson's disclosure and expresses that they do not suggest or teach the aforementioned features of the present claim(s). However, Applicant does not state why these particular disclosures do not read on the claims. Therefore, Examiner has no basis to refute Applicant's allegations, and as such, firmly still believes that the cited passages read on the features in question. However, for advancement of prosecution, Examiner has provided detailed explanations in the rejection of Claim 1 as to why Examiner believes Wilson reads on the claims.

For example, Wilson provides means for reading the images and calculating position and inclination of the axis of the hole based on shape and dimensions of the hole shown in the images for the following reason(s):

The "dark circle" is used to align the aiming guide, associated it with the head, with the nail hole. Since it is known that the longitudinal axis of the reference system aligns parallel with the x-ray beam for the dark circle to appear (col. 5, ll. 3 – 8), and the dark circle represents the alignment of the instrument and reference system, and is used to assist in ensuring proper alignment of these components with the hole, and the dark circles are "superimposed on the over the circular image of the nail hole (col. 5, ll. 28 – 41), the position and inclination of the axis of the hole would also be realized based on the same image depicting the dark circles.

Applicant submits also that Wilson also does not disclose an automatic pointing apparatus as recited in claim 1. Instead, Wilson teaches that the largest component of the handle

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(1) is the grip portion (3) into which are formed grooves (2) to improve the surgeon's hold on the aiming guide during surgery.

In response, Examiner points out respectfully that:

1) The recitation of “automatic” is placed in the *preamble* of the claim and features placed in the preamble and not the body of the claims, and therefore is NOT actually a statement of limiting structure and is not given patentable weight. See *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) (“where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation”); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim); *STX LLC. v. Brine*, 211 F.3d 588, 591, 54 USPQ2d 1347, 1350 (Fed. Cir. 2000) (holding that the preamble phrase “which provides improved playing and handling characteristics” in a claim drawn to a head for a lacrosse stick was not a claim limitation). Compare *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333-34, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003). See also *Corning Glass Works*, 868 F.2d at 1257, 9 USPQ2d at 1966.

2) Providing an automated process or apparatus in and of itself would not provide one with a patentable distinct feature under 35 U.S.C. §103(a). It should be noted that it would be obvious to one of ordinary skill in the art to modify Wilson to automate the use of the aiming guide (e.g. attach a robot to the aiming guide and have it monitor the matching of the dark concentric circles), since it has been held broadly that providing an automatic or mechanical

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means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art, and involves only routine skill in the art. See *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).

Since, as explained in bullet #1, automation of the apparatus is not being positively recited in the body of the claims and is not providing any distinctions or limitations to the claims, the present 35 U.S.C. §§102(a) and 102(e) rejections are still valid.

Claims 5 - 11 are still rejected under 35 U.S.C. §103(a).

5. Applicant's amendments to the claims, filed January 6, 2012, with respect to the specification and claims have been fully considered and are persuasive. The objections to specification and rejections of Claim 2 – 4 under 35 U.S.C. §112 second paragraph have been withdrawn.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Thursday (8:30 am - 5:30 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./  
Examiner, Art Unit 3777

/Tse Chen/  
Supervisory Patent Examiner, Art Unit 3777